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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,567	03/23/2001	Fred T. Parker	PA-5245-RFB	6497

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COOK GROUP PATENT OFFICE
P.O. BOX 2269
BLOOMINGTON, IN 47402

EXAMINER
RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 02/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary	Application No.	Applicant(s)	
	09/815,567	PARKER, FRED T.	
	Examiner	Art Unit	
	Anu Ramana	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's response to the Office Action dated January 13, 2003 has been considered and this Office Action is responsive thereto.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4-5, 10-13, and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. (US 5,792,124) in view of Park et al. (US 6,159,187).

Regarding claim 1, Horrigan et al. disclose a catheter or sheath having a unitary lubricous liner or inner tube 40; a reinforcement means or wire braid 35 terminating proximal to the distal end of inner tube 40; a first outer tube 15; a second outer tube 20 wherein the second outer tube 20 is made of softer material than the first outer tube 15 (Figure 3; col. 2, lines 60-67; col. 3, lines 1-20; and col. 8, lines 28-34); and a distal tip 45. Further, Horrigan et al. teach the use of wire braid 35 to offer better kink resistance (col. 5, lines 1-3).

Horrigan et al. do not disclose the use of a flat wire coil as a reinforcement means.

Park et al. teach a catheter section or sheath with a braided wire coil (Figure 7) for better kink resistance (col. 2, lines 40-43; col. 13, lines 64-67; and col. 14, lines 1-26). Further, Park et al. teach the importance of designing the sheath to enable its manipulation through increasingly small blood vessels (col. 1, lines 30-52).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the wire braid 35 of Horrigan et al. with a braided wire coil as disclosed by Park et al. to have facilitated the manufacture of the catheter or sheath with a diameter suitable for application in an environment of increasingly small diameters.

Regarding claim 2, Horrigan et al. disclose that the materials of the outer jacket of the sheath including the inner tube 40, wire braid 35, first outer tube 15 and second outer tube 20 are bonded (col. 5, lines 47-56).

Regarding claim 4, Horrigan et al. further disclose that the inner tube 40; the wire braid 35; the first outer tube 15 and the second outer tube 20 are fused or bonded by heating (col. 5, lines 47-56).

Regarding claim 5, although the Horrigan et al. device does not include a radiopaque marker band, attention is again directed to Park et al., which disclose a radiopaque marker band 120 in the distal region of a catheter or sheath 114 to allow viewing of the position of the distal most portion of the sheath 114 (col. 9, lines 25-33). Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radiopaque marker band 120 as taught by Park et al. in the second outer tube 20 of the Horrigan et al. device for viewing the position of the distal tip 45 of the Horrigan et al. device.

Regarding claims 10-13, Horrigan et al. further disclose a second outer tube 20 made of a material having a hardness range of Shore durometer 25D to 40D and a first outer tube 40 having a hardness range of Shore durometer 50D to 60D.

Regarding claim 15, Park et al. teach a wire coil 232 made of one or more ribbons or "flat wire"(Figure 7 and col. 14, lines 15-17).

Regarding claim 16, Park et al. teach a sheath 110 having an arcuate distal tip region 112 (Figure 2 and col. 9, lines 21-24).

Regarding claim 17, Park et al. teach a sheath 110 having an arcuate distal tip region 112 with a typical length of 2.5 cm to 30 cm (col. 9, line 40).

Regarding claim 18, Park et al. teach a sheath 110 having an arcuate distal tip region 112 that is a quadrant of a circle (Figure 2 and col. 9, lines 21-24).

Regarding claim 19, Horrigan et al. disclose that the wire braid 35 should not extend more than 1/3 the length of the second outer tube 20 to provide optimum flexibility of tip 45 (col. 5, lines 1-9) or approximately 3 mm (col. 5, lines 16-20).

Regarding claim 20, Horrigan et al. disclose a sheath having a unitary lubricous liner or inner tube 40.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. in view of Park et al. as applied to claim 1 above, further in view of Parker (US 5,380,304).

Although Horrigan et al. do not disclose a roughened surface, attention is directed to the Parker reference, which teaches an inner tube 22 having an outer rough surface; a wire coil 23; and an outer tube 12 wherein the outer tube 12 is mechanically connected or bonded to the inner tube 22 and the wire coil by the well-known heat shrinking and formation process (col. 3, lines 67-68 and col. 4, lines 1-3).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the sheath of Horrigan et al. by roughening the outer surface of inner tube 22, as taught by Parker, in order to improve bonding between the outer tube 12, the wire coil 23 and the inner tube 22.

Claims 6-9 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. in view of Park et al., further in view of Ju et al (US 5,599,325).

Regarding claim 6, Horrigan et al. do not disclose a sheath wherein the second outer tube 20 of the sheath contains radiopaque filler.

Ju et al. teach a sheath 10 wherein the distal end portion of the stem member 34 is a soft tip member 40 made from a polymer and radiopaque filler blend (col. 6, lines 6-14).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a second outer tube 20 in the sheath of Horrigan et al. wherein the second outer tube 20 is made from a blend of polymer and radiopaque filler as taught by Ju et al. in order to allow viewing of the position of the sheath in the human body.

Regarding claim 7, Ju et al. further disclose a sheath 10 with an outer layer containing 0 to 42 percent by weight of radiopaque filler, which is the claimed range of about 20% to 85%.

Regarding claim 8, Ju et al. disclose a sheath 10 with a second outer tube containing 0 to 42 percent by weight of radiopaque filler, which is "about 80%" as claimed.

Regarding claim 9, Ju et al. further disclose a sheath 10 with a first outer tube containing 0 percent by weight of radiopaque filler, which is substantially free of radiopaque filler.

Regarding claim 21, see the discussion for claims 1, 6, 10, 15, 17 and 19.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. in view of Park et al. as applied to claim 1 above, further in view of MacDonald et al (US 6,210,396).

Horrigan et al. do not disclose a sheath wherein the first outer tube 15 and the second outer tube 20 are of different colors or shades.

MacDonald et al. teach a catheter body or sheath 15 having a sleeve 120, a distal catheter shaft 35, a radiopaque band 140 and a distal soft tip 40 wherein the color of the sleeve 120 is different from the color of the distal catheter shaft 35, the color of the radiopaque band 140 and the color of the distal soft tip 40 for identification purposes (col. 10, lines 57-62).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided different colors to the first outer tube 15 and the second outer tube 20 in the sheath of Horrigan et al. as taught by MacDonald in order to enable a user to identify the first and the second tubes.

Response to Arguments

Applicant's arguments filed on January 13, 2002 have been fully considered but are not persuasive.

Regarding page 2 of the Remarks section, in response to applicant's argument that Horrigan and Park do not teach a thin-walled device, the Examiner notes that applicant's claims are silent as to the dimensions (wall thickness and outer diameter) of the introducer sheath of the instant invention. Since intravascular devices are used in an environment of small diameters they must be sized to fit the specific diameter of the vasculature of intended use.

The Examiner respectfully disagrees with Applicant's argument that the combination of Horrigan et al. and Park et al. do not disclose the claimed invention. Horrigan et al. disclose the use of wire braid 35 as reinforcement for a thin wall guiding catheter or "intravascular device" (col. 4, lines 21-22). Park et al. teach a "braided wire coil" with one or more ribbon coils (col.

14, lines 13-26) for the purpose of reinforcing intravascular devices with small overall diameters for exceptional kink resistance (col. 2, lines 40-43). Thus, Horrigan et al. and Park et al. disclose the claimed invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:30 am and 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR
February 11, 2003

PEDRO PHILOGENE
PRIMARY EXAMINER